



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket No. FDA-2014-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Bambermycins; Hygromycin B; Lincomycin; Pyrantel; Tylosin; Tylosin and Sulfamethazine; Virginiamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 19 new animal drug applications (NADAs) for certain Type A medicated articles and Type B medicated feeds. This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, [john.bartkowiak@fda.hhs.gov](mailto:john.bartkowiak@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: The following 5 sponsors have requested that FDA withdraw approval of the 19 NADAs listed in the following tables because the products are no longer manufactured or marketed:

- ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115:

NADA	Product Name
091-582 <sup>1</sup>	Gilt Edge TYLAN (tylosin phosphate) Mix
108-484 <sup>1</sup>	HFA Tylosin-10 Plus Sulfa (tylosin phosphate and sulfamethazine)
110-045 <sup>1</sup>	Good Life TYLAN 10 (tylosin phosphate) Premix
110-439 <sup>1</sup>	HFA HYGROMIX 0.48 (hygromycin B) Medicated Premix
128-411 <sup>1</sup>	TYLAN 5 Sulfa (tylosin phosphate and sulfamethazine) Premix

- Micro Beef Technologies LTD, P.O. Box 9262, Amarillo, TX 79105:

NADA	Product Name
138-187 <sup>1</sup>	TYLAN 40 or 100 (tylosin phosphate)

- Ridley USA, Inc. d/b/a Ridley Feed Ingredients, 1609 1st Ave., P.O. Box 110, Mendota, IL 61342:

NADA	Product Name
099-468 <sup>1</sup>	Waynextra for Swine (tylosin phosphate)
131-958 <sup>1</sup>	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)
132-136	Ban-A-Worm II (pyrantel tartrate)

- Provimi North America, Inc., 6531 State Rte. 503, Lewisburg, OH 45338:

NADA	Proprietary Name
103-089 <sup>1</sup>	TYLAN 5, 10, 20, or 40 (tylosin phosphate)
118-814	WORM-BAN 5 or 10 (pyrantel tartrate)
127-508 <sup>1</sup>	HYGROMIX 0.6 (hygromycin B)
131-413	FLAVOMYCIN 0.4 or 2 (bambermycins)
133-333 <sup>1</sup>	STAFAC 10 (virginiamycin)

- Virbac AH, Inc., 3200 Meacham Blvd., Fort Worth, TX 76137:

NADA	Proprietary Name
013-214 <sup>1</sup>	PURINA HYGROMIX (hygromycin B) for Swine
042-660 <sup>1</sup>	PURINA Pork-Plus (tylosin phosphate and sulfamethazine)
043-387 <sup>1</sup>	PURINA Hog Plus II (tylosin phosphate)
099-767 <sup>1</sup>	PURINA TYLAN 40 (tylosin) Plus Sulfamethazine
132-574 <sup>1</sup>	PURINA Check-R-Ton LI (lincomycin hydrochloride)

<sup>1</sup>The NADAs listed were identified as being affected by guidance for industry (GFI) #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209", December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of the NADAs listed in this document, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: April 4, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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